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John C. Lewin, M.D.

October 15, 2010

Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius,

The American College of Cardiology is pleased to comment on the National Health Care Quality Strategy and Plan. The College is a 39,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. We appreciate the opportunity to provide input for the National Health Care Quality and Strategy.

The ACC has been at the forefront of measuring and improving quality of care for patients with cardiovascular disease with the development of clinical guidelines, performance measures, appropriate use criteria, and clinical registries. The work that ACC has done on this front has contributed enormously to the care for cardiovascular disease. We believe wholeheartedly in the power of applying clinical practice guidelines, collecting and reporting performance data, and sharing practical strategies to improve the quality of care for patients with cardiovascular disease. The results of this investment in quality have been extraordinary – a dramatic drop in mortality for patients who suffer heart attacks over the past ten years. The College is committed to not only continuing cardiology's relentless drive to improve the quality of cardiovascular care, but also to working with the entire healthcare community to improve the outcomes and experience of care for all patients. The Affordable Care Act (ACA) has granted HHS broadened authority and responsibility for improving the quality of health care Americans receive and for putting the nation on a path toward sustainable health care costs. We believe that if our nation is to make significant progress toward these goals, physicians must be engaged as full partners at all levels – national policymaking, community leadership, practice leadership, and the

individual physician-patient relationship. We are heartened by the Strategy's emphasis on the need for strong public-private partnerships.

Overall, the ACC commends HHS for launching the development of the Strategy and for structuring a process for public participation that begins to identify the key issues and ask the right questions. We recognize that the Strategy is of necessity fairly broad and nonspecific at this point. However, the lack of specificity does pose challenges to providing constructive input. Specifics will be needed to provide clarity about what programs and initiatives align with the plan and to hold everyone accountable for results. Meeting the ACA mandate to submit a complete Strategy to Congress by January 1 will require significant and rapid work on the part of HHS. We urge you to continue to solicit feedback from the public as you refine the Strategy over the next few months, and we welcome the opportunity to provide input on specific initiatives, approaches, and proposed programs.

The ACC's responses to the feedback questions follow. Where relevant, the responses cite a number of ACC projects and initiatives to illustrate how the elements of the Strategy could be carried out. We recommend that the Department consider including similar examples in the Strategy to make it more concrete. We welcome the opportunity for further discussion with HHS to ensure that our shared goals can align on these projects or lead to the development of new projects.

Question 1: Are the proposed Principles for the National Strategy appropriate? What is missing or how could the principles be better guides for the Framework, Priorities and Goals?

The ACC supports the guiding principles outlined for the Strategy:

- Person-centeredness and family engagement will guide all strategies, goals, and improvement efforts
- The strategy and goals will address all ages, populations, service locations, and sources of coverage
- Eliminating disparities in care – including but not limited to those based on race, ethnicity, gender, age, disability, socioeconomic status and geography – will be integral to all strategies and goals
- The design and implementation of the strategy will consistently seek to align the efforts of public and private sectors

These core principles guide many of the ACC's quality initiatives and programs. For example:

- CardioSmart, the ACC's patient focused website provides tools to help cardiovascular professionals assist their patients in learning more about their conditions and treatments and becoming more active participants in their care.
- The ACC National Cardiovascular Data Registry (NCDR) comprises a suite of six clinical data registries that focus on a variety of cardiovascular patient populations and services: Cath-PCI (diagnostic cardiac catheterization and percutaneous coronary interventions), ACTION Registry-Get with the Guidelines (acute coronary syndrome patients), ICD (implantable cardioverter-defibrillator procedures), CARE (carotid revascularization by catheter and by endarterectomy), IMPACT (congenital heart disease procedures), and PINNACLE (ambulatory cardiovascular care).
- In 2009, the American College of Cardiology (ACC) launched *credo*, the Coalition to Reduce Racial & Ethnic Disparities in CV Outcomes, to provide cardiovascular (CV) professionals with

evidence-based tools that would help them serve their diverse patient populations better and improve patient satisfaction and outcomes.

- The ACC Medical Directors' Institute (MDI) brings together practicing cardiologists and health plan leaders to identify common goals for improving care and to develop joint strategies and projects to work toward those goals.

Although we do strongly support the proposed core principles, we recommend the addition of another principle to reflect the critical role of health professionals. The ACC urges HHS to consider adding this core principle:

- *The strategy and goals will engage health professionals at every level of design, implementation, and evaluation.*

The addition of this principle would make clear the important role of those professionals who provide the care to the citizens of this country and who are best equipped to guide national plans on the strategy and goals. By working closely with these professionals, HHS can ensure that the needs of the individual patient are put first.

Question 2: Is the proposed Framework for the National Strategy sound and easily understood? Does the Framework set the right initial direction for the National Health Care Quality Strategy and Plan? How can it be improved?

The ACC agrees that the proposed three-pillared framework of better care, affordable care, and healthy people/healthy communities is sound and easily understood. However, ACC urges that HHS not oversimplify or suggest that the way forward is clear and easily or rapidly achievable. Issues of improving care, making care more affordable, and ensuring the health of populations and communities are all complex and achieving significant progress will be challenging. We recommend that this document explicitly acknowledge the iterative nature of this transformation and discuss the barriers and challenges as a first step toward identifying realistic goals and actionable plans for accomplishing those goals. In addition, further discussion of what is meant by each component of the framework would be helpful. For example, it is highly unlikely that anyone would dispute that better care and affordable care should be essential elements of the framework. It is virtually certain, though, that there will be significant disagreement about what constitutes better care and what is affordable.

Many of ACC's signature quality initiatives clearly illustrate the elements of the framework. For the past thirty years the ACC has partnered with the American Heart Association (AHA) to lead the development of clinical practice guidelines for cardiovascular care. The guidelines are based on careful review of available efficiency data and clinical trial results and include recommendations that define a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. To date, the ACC/AHA partnership has produced 18 published guidelines that encompass more than 2800 recommendations for cardiovascular care. The ACC/AHA collaboration extends to the development of performance measures – specific clinical measures for physicians that are indicative of high quality, evidence-based care. The performance measures, developed according to a rigorous and peer-reviewed methodology, capture aspects of care recommended in ACC/AHA clinical practice guidelines that have been proven to improve patient outcomes and that can be measured in valid, actionable, and feasible ways.

We have also developed appropriate use criteria (AUC), which define “when to use” and “how often to use” a given procedure or treatment in the context of scientific evidence, the health care environment, the patient’s profile and a physician’s judgment. Appropriate use criteria provide practical tools to measure variations in care patterns. The criteria are designed to examine the use of diagnostic and therapeutic procedures to support efficient use of medical resources, while also providing patients with high quality, scientifically sound care. The criteria are developed by panels of clinical experts from the ACCF, other relevant professional societies, and payer organizations. The panels assess the benefits and risks of a procedure for different indications or patient scenarios and then determine whether the indication is “appropriate,” “uncertain” or “inappropriate.” The criteria are also based on current understandings of the technical capabilities and potential patient benefits of the procedures examined—meaning future evidence development may require these ratings to be updated. Because of its patient-centered approach, it is hoped that appropriate use criteria will be used to guide future research and lead to patient education regarding expected benefits and risks associated with diagnostic and therapeutic procedures. In addition, physicians, payers and medical facilities can use the criteria prospectively or retrospectively to assess practice patterns, design ordering protocols and/or provide the basis for quality improvement activities focused on ensuring the most appropriate care for patients. Implementation of the AUC in practice will lead to better care by ensuring that patients receive the right test at the right—and first-- time and will also help to make care more affordable by reducing the inappropriate use of services.

In addition to the development of tools that can be used by others, the ACC has created and led projects aimed to improve healthcare. For example, the ACC’s Door to Balloon (D2B) Alliance demonstrates the power of a data-driven, evidence-based quality improvement initiative to improve individual patient outcomes and community health. Launched in 2006, the D2B Alliance brought together more than 1,000 U.S. and international hospitals to provide practical strategies and tools for speeding the delivery of life-saving heart attack care. The campaign produced significant improvements in the timeliness of interventions in heart attack patients, resulting in improvements in outcomes and a reduction in costs. The 1000 participating centers across the U.S. have significantly reduced variation in myocardial infarction treatment, in addition to reducing the average length of hospital stay by 2 days and average cost by \$30,000 per admission. The D2B initiative has progressed to a maintenance phase called D2B: Sustain the Gain.

The ACC, in partnership with the Institute for Healthcare Improvement, launched Hospital to Home (H2H): Excellence in Transitions, an effort to improve the transition from inpatient to outpatient status for individuals hospitalized with cardiovascular disease. The H2H project aims to create a rapid learning community where hospitals, physicians, and community organizations can share their knowledge and best practices regarding this critical transition. H2H’s goal is to reduce all-cause readmission rates among patients discharged with heart failure or acute myocardial infarction by 20 percent by 2012. Readmissions are not only a great cost to Medicare, but often represent a failure of the healthcare system to be person-centered as the department envisions. By ensuring that there is coordination around a time when people are most vulnerable, we demonstrate our accountability for safe and effective transitions and for good stewardship of healthcare resources. This initiative aims to link all those who care for and about patients in a common goal.

Question 3: Using the legislative criteria for establishing national priorities, what national priorities do you think should be addressed in the initial National Health Care Quality Strategy and Plan?

Better care

The ACC believes that adherence to evidence based practice guidelines can make an enormous positive impact on patient care. As noted above, we have invested heavily in developing and updating evidence based guidelines. Other professional societies have done so as well. The guidelines are of little use in improving care, though, unless physicians have access to critical information at the point of care, can measure their adherence within the flow of care, and receive timely feedback and targeted recommendations for improving practice. We recommend that the Strategy include as priorities:

- Provision of clinical decision support and evidence based guidelines at the point of care.
- Strengthening the science of performance measurement and facilitating data submission, reporting, and feedback to providers.
- Developing and disseminating proven strategies for improving performance.
- Integrating the above approaches into effective continuing professional development and education.
- Recognition and reward for systematic quality improvement practices and performance

Priorities for better care must include making health care safer by reducing adverse events. The ACC urges that the Strategy's priorities include ensuring that the Food and Drug Administration has adequate resources to maintain scientifically rigorous and efficient new product review processes and enforce necessary post-market surveillance requirements. Clinical data registries like the NCDR can be powerful tools for helping the FDA and industry identify and solve safety issues with drugs and medical devices. Enhanced post-market surveillance capabilities will help to provide the confidence in safety and effectiveness necessary to provide patients with timely access to critical advances in medical device and pharmaceutical technology.

We also recommend that that Strategy identify priorities for specific areas of health conditions. The ACA criteria that emphasize high cost chronic conditions and the potential for high impact clearly point to placing a priority on cardiovascular care. The ACC is eager to work with HHS to more fully develop specific priorities for quality improvement for cardiovascular care and related chronic conditions.

Finally, we recommend that continuing professional development be highlighted as an important approach to improving healthcare. The ACC is not only the leading educator of cardiologists and other cardiovascular disease care experts throughout their careers, but also a leader in developing more effective and evidence-based continuing education. Continuing education has been shown to be effective in improving quality, especially when the education is clinically-relevant and ongoing. As noted in the 2010 Institute of Medicine report, *Redesigning Continuing Education in the Health Professions*, transformed continuing medical education—continual professional development (CPD)—is central to improving health care quality and patient safety. All efforts to promote quality should be partnered with professional and lifelong learning strategies, including point-of-care learning, team-based learning, and data-driven performance improvement. This will not only assure improved quality in

healthcare but will serve to align QI and educational requirements for clinicians and their systems of care, with all rowing in the same direction toward improved patient care and outcomes.

Affordable care

The ACC is very concerned by the rapid and continuing growth of healthcare costs. While these expenditures contribute to lives saved and significant improvement in quality of life for many Americans, the growth in spending appears to be unsustainable in the long term. The ACC believes fundamental reform of payment and delivery systems is needed to ensure that all Americans receive high quality, efficient care. We support carefully designed changes in payment systems and urge HHS to identify as a high priority testing of new payment models that provide rewards for quality improvement and support for the infrastructure needed to make those changes at the community and practice level. ACC believes the good news in efforts to bend the cost curve is that the best quality care can be the most affordable. Initiatives to reduce hospital admissions and preventable readmissions, decrease unnecessary tests and procedures, and improve prevention and chronic disease management will both enhance quality and control costs.

Priorities for making health care more affordable must also address waste in the health care system. Strategies for improving care, such as adherence to clinical guidelines, will reduce the amount of ineffective and inappropriate care being provided. However, significant progress toward a more affordable system cannot occur without also reducing the level and amount of unproductive administrative activity that now consumes too many of our health care resources. Despite previous legislative efforts to reduce administrative burden, the administrative burden of healthcare and physician practice has only grown in recent years. The ACC urges HHS to make reducing administrative burdens for physicians and other health care providers a priority for the Strategy.

Healthy people/healthy communities

The ACC believes that person-centered care must be community based care. Clinical integration offers many potential benefits for both patients and providers. New models of organizing and delivering health care services are needed to strengthen care coordination, improve quality, and enhance efficiency and we are eager to contribute to the testing and diffusion of such models. Many such models of care emphasize interdisciplinary care and provider communication and coordination, notably the patient-centered medical home (PCMH), community health teams, and accountable care organizations (ACOs). We believe such models have potential to improve care, particularly for patients with complex chronic conditions such as cardiovascular disease. We support their emphasis on strengthening the capacity of primary care. However, the ACC strongly urges HHS to acknowledge the importance of specialty care and the critical role of specialty physicians in new models of care such PCMH and ACOs. We cannot emphasize strongly enough that for a patient whose major health problem is cardiovascular, the cardiologist is often best suited to manage the patient and coordinate care with other physicians. Given both the complexity of the growing number of patients with complex chronic conditions and the recognized scarcity of primary care physicians, the ACC recommends that the need for specialists such as cardiologists to be able to coordinate care in models like the PCMH or an ACO be explicitly acknowledged. Rigid adherence to exclusively primary care centered models risks providing sub-optimal care for complex patients.

Concurrent with the growing recognition of the importance of community based care, increasing numbers of cardiologists are closing their practices and moving to hospital-based employment due, in large part, to unsustainable financial pressures. The acquisition of so many cardiology practices by hospitals raises serious concern about the availability of the full range of community based, high quality cardiovascular care in many localities. The ACC recommends that priorities for healthy communities include addressing the financial viability of providing high quality care in the communities where patients live and work.

Question 4: What aspirational goals should be set for the next 5 years, and to what extent should achievable goals be identified for a shorter timeframe?

The Strategy should set aspirational goals to clearly articulate a vision for improving quality. Such goals are needed to not only to inspire, but to focus energy and resources. We recommend that HHS consider the following aspirational goals:

- Establish a public private partnership to save one million lives from preventable cardiac events by 2014 – the Million Hearts Campaign.
- By 2014 75% of US physicians who care for Medicare and Medicaid patients with chronic diseases and co-morbidities will use interoperable clinical decision support and registry systems linked to electronic health records to promote evidence based, patient centered care and systematic quality improvement.

Targeted goals that can be accomplished within a shorter timeframe are also critical to maintain forward progress, avoid discouragement, and to correct course as needed. For example, the ACC has committed to:

- Reduce preventable readmissions for patients discharged with heart failure or myocardial infarction by 20 percent by 2011. The H2H initiative highlighted earlier focuses on this goal.
- Reduce the percentage of inappropriate cardiovascular imaging by 15 percent. More than 100 cardiology practices have volunteered to participate in ACC's Imaging in FOCUS program which provides a tool for measuring patterns of imaging appropriateness and offers strategies for improvement.

Additional targets that inform ACC's educational portfolio include:

- Increase anticoagulation in at-risk atrial fibrillation patients to more than 90 percent.
- Continued development of regional STEMI systems of care, so that median door-to-balloon time for transferred STEMI patients is less than 90 minutes.

Question 5: Are there existing, well-established and widely used measures that can be used or adapted to assess progress towards these goals? What measures would guide public and private sector action, as well as support assessing the nation's progress to meeting the goals in the National Quality Strategy?

The ACC has developed performance measures for many years, focusing on the most impactful areas of cardiovascular health, particularly coronary artery disease and congestive heart failure. In developing these measures, the ACC has worked with a series of partners, including the AHA, the American Medical Association Physician Consortium for Performance Improvement, the National Quality Forum

and others. We believe that the development of these measures through the stakeholder groups allows for broad input into the measures to ensure they are appropriately crafted.

The ACC strives to develop measures that are supported by strong evidence and that will demonstrate a meaningful difference in outcomes of care. In recent years, the ACC and its partners have worked on the development of outcome measures that use the power of combined claims and clinical registry data to create performance measures of morbidity and mortality for cardiac interventions. While these measures are likely more meaningful than the process measures created earlier, they are also more difficult to use, requiring careful risk adjustment in order to ensure that differences are related to the work of the providers and not the patient population. The College is also committed to the identification of limitations and unintended consequences of these measures and to the development of innovative composites and other practical and meaningful core sets of measures.

In considering the priority measures as it develops a quality plan for the nation, the ACC believes that HHS should continue to focus on those conditions that have the highest impact on the nation. As the leading cause of death for Americans and a considerable cause of morbidity as well, measures of care for heart disease should be at the top of the list.

Question 6: The success of the National Health Care Quality strategy and Plan is, in large part, dependent on the ability of diverse stakeholders across both the public and private sectors to work together. Do you have recommendations on how key entities, sectors or stakeholders can best be engaged to drive progress based on the National Health Care Quality Strategy and Plan?

All stakeholders in the National Health Care Quality Strategy and Plan – patients, families, communities, providers, employers, policy makers, industry --must have a voice in developing and implementing the strategy and in ongoing assessment of its success. Active engagement and meaningful roles for physicians, nurses and other healthcare professional, hospitals, and other facilities will be critical to success as most of the burden of and opportunity for implementing quality strategies will fall on them. The efforts HHS has undertaken during this initial public comment period, including outreach by key policymakers to professional societies and provider organizations are an important step. Professional societies such as the ACC provide an excellent means for getting physicians and other health care professional engaged and invested in the process. Physicians place a high level of trust in their specialty societies and professional organizations. We strongly encourage HHS to continue efforts to engage professional societies in the design, implementation, and evaluation of the Strategy.

Question 7: Given the role States can play in organizing health care delivery for vulnerable populations, do the Principles and Framework address the needs and issues of these populations?

The core principles and framework provide a strong starting point for addressing the needs of vulnerable populations. However, additional focus will be needed to ensure that the quality of care for patients with special needs improves. HHS may wish to consider establishing specific priorities and goals established for vulnerable populations. Within the cardiovascular sphere, for example, congenital heart disease patients require specialized care throughout a lifetime. Issues of better, safer care, family and community engagement, and affordability are key concerns as children with congenital heart defects survive into adulthood. Successful programs for vulnerable populations, including State-based

programs for children with special health care needs, may offer lessons for improving person-centered care, family and community engagement, and care coordination.

Regional differences, often combined with racial and ethnicity disparities in cardiovascular disease prevalence, morbidity, and mortality also would benefit from a regional and state-based focus. Support for educational and quality improvement programs regionally targeted to the most vulnerable populations and inclusive of communication strategies that incorporate principles of health literacy and cultural competency, will serve to provide the highest level of support for strained healthcare providers and systems as well as maximally improve overall healthcare quality and costs.

Thank you for the opportunity to offer the ACC's recommendations. I also offer the ACC's commitment to work with the Department as an active, engaged partner in the development and implementation of the National Health Care Quality Strategy and Plan. Working together we can make great progress toward providing high quality, patient-centered, affordable care for all Americans. If you have questions about our recommendations or if the College can be of any assistance, please contact Rebecca Kelly, Senior Director, Regulatory Affairs at 202-375-6398 or rkelly@acc.org

Sincerely,

A handwritten signature in blue ink that reads "Ralph Brindis". The signature is fluid and cursive, with the first letters of each name being capitalized and prominent.

Ralph Brindis, MD, MPH, FACC
President

Cc: Jack Lewin, MD, CEO